Background and Brief Description

CDC provides technical guidance to the Department of Health and Human Services (HHS) in coordination with the Centers for Medicare & Medicaid Services (CMS) and the Food and Drug Administration (FDA) for the implementation of the Clinical Laboratory Improvement Amendments (CLIA). The Clinical Laboratory Improvement Amendments of 1988 (CLIA) directed the Secretary of Health and Human Services to establish the maximum number of cytology slides that any individual may screen in a 24 hour period; to establish certain quality assurance standards; to set personnel standards; and to provide for periodic proficiency testing of cytotechnologists and pathologists involved in screening and interpreting cytological preparations.

The regulations implementing CLIA, published in the **Federal Register** of February 28, 1992, established that the maximum number of slides examined by an individual in each 24 hour period was not to exceed 100 slides and could not be examined in less than an eight hour day. The regulation further established that the technical supervisor is required to evaluate the performance of cytotechnologists at least every six months and determine their individual maximum daily workload limit. In 1992, when the regulation was published, all Pap slides were conventional ''Pap smears.'' In a conventional Pap smear, samples are smeared directly onto a glass microscope slide after collection. The cells are often obscured by blood or the smear may be too thick and contain contaminating artifacts. Today, almost all Pap tests in the U.S. are collected with a liquid-based method. Instead of ''smearing'' cervical cells directly onto a glass microscope slide, the cells are sent to the laboratory in a liquid preservative and processed by an automated processor. This processor disperses a uniform thickness representative sample on the slide that is free of obscuring blood, mucus, and non-diagnostic debris in a circle that covers less than one half of the slide.

CLIA's Federal Advisory Committee, the Clinical Laboratory Improvement Advisory Committee (CLIAC), has discussed cytology workload on numerous occasions from 1996 until present. On August 29, 2011 the American Society of Cytopathology's (ASC) Executive Board approved an ASC task force recommendation that the average laboratory cytotechnologist productivity should not exceed 70 slides and that an individual's screening time should not exceed seven (7) hours in a 24 hour period.

Each laboratory will receive an advance request to participate in the Image-Assisted Cytology Workload Practices Survey from a DLSS contractor that has been selected to collect the survey data and conduct the time measure study. Respondents will be cytology supervisors from the 1,245 cytology laboratories in the Unites States. Since a response to this survey is voluntary we would expect an 80% response rate or approximately 996 laboratories. Responses would be submitted in written format. The estimated burden per response is one half hour. In addition, individual cytotechnologists working in the laboratory will be asked to complete the Image-Assisted Cytology Workload Assessment Survey. There are 6,064 cytotechnologists in the United States. Response to this survey is voluntary, so we would expect an 80% response rate or approximately 4,581 cytotechnologists. Responses would be submitted in written format. The estimated burden per response is one half hour. CDC requests OMB approval to collect information for one year.

There are no costs to respondents other than their time.

The total estimated annual burden hours are 2,789.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Cytology Supervisor	Image-Assisted Cytology Workload Practices	996	1	30/60
Cytotechnologists	Image-Assisted Cytology Workload Assessment.	4,581	1	30/60

Leroy Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day–13–0199]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–7570 and send comments to LeRoy Richardson, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should

be received within 60 days of this notice.

Proposed Project: Importation of Etiologic Agents (42 CFR 71.54) (OMB Control No. 0920–0199, exp. 1/31/2014)—Revision—Office of Public Health Preparedness and Response (OPHPR), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 361 of the Public Health Service Act (42 U.S.C. 264), as amended, authorizes the Secretary of Health and Human Services to make and enforce such regulations as are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. Part 71 of Title 42, Code of Federal Regulations (Foreign Quarantine) sets forth provisions to prevent the introduction, transmission, and spread of communicable disease from foreign countries into the United States. Subpart F—Importations—contains provisions for the importation of infectious biological agents, infectious substances, and vectors (42 CFR 71.54); requiring persons that import these materials to obtain a permit issued by the CDC.

CDC requests Office of Management and Budget approval to collect information for three years using the Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States and Application for a Permit to Import or Transport Live Bats. We are also requesting a title change to read—*Application for Permit to Import Infectious Biological Agents into the United States (42 CFR 71.54.*

The Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States form is used by laboratory facilities, such as those operated by government agencies, universities, and research institutions to request a permit for the importation of biological agents, infectious substances, or vectors of human disease. This form currently requests applicant and sender contact information; description of material for importation; facility isolation and containment information; and personnel qualifications. CDC plans to revise this application to request information on where the imported material will be stored at the recipient facility and who would be responsible for this location; verification that the permittee has implemented biosafety measures commensurate with the hazard posed by the infectious biological agent, infectious substance, and/or vector to be imported, and the level of risk given its intended use; and a secondary contact information for the permittee to provide in case the permittee is unavailable. These additional data requests will not affect the burden hours.

The Application for Permit to Import or Transport Live Bats form is used by laboratory facilities such as those operated by government agencies, universities, research institutions, and for educational, exhibition, or scientific purposes to request a permit for the importation, and any subsequent distribution after importation, of live bats. This form currently requests the applicant and sender contact information; a description and intended use of bats to be imported; and facility isolation and containment information. CDC plans to revise this application to request secondary contact information for the permittee to provide in case the permittee is unavailable. These additional data requests will not affect the burden hours.

Estimates of burden for the survey are based on information obtained from the CDC import permit database on the number of permits issued on annual basis since 2010. The total estimated burden for the one-time data collection is 545 hours.

There are no costs to respondents except their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Applicants Requesting to Import Biological Agents, Infectious Substances and Vectors.	Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States.	1,625	1	20/60	542
Applicants Requesting to Import Live Bats.	Application for a Permit to Import Live Bats.	10	1	20/60	3
Total					545

LeRoy Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2013–21974 Filed 9–9–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1064]

Agency Information Collection Activities; Proposed Collection; Comment Request; Application for Participation in the Medical Device Fellowship Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the application for participation in the Medical Device Fellowship Program.